

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in Exhibit A
attached hereto

ORDER ADOPTING
MEMORANDUM OPINION AND ORDER
(*Daubert* ruling re: Elizabeth Mueller, M.D.)

On October 20, 2017, defendants filed a Notice of Adoption of Prior *Daubert* Motion of Elizabeth Mueller, M.D. for Wave 6. [ECF No. 4829]. The court **ORDERS** that the Memorandum Opinion and Order (*Daubert* Motion re: Elizabeth Mueller, M.D.) [ECF No.6262] entered on July 23, 2018 as to the Ethicon Wave 4 cases is **ADOPTED** in the Wave 6¹ cases identified in Exhibit A. The Memorandum Opinion and Order (*Daubert* Motion re: Elizabeth Mueller, M.D.) is attached hereto as Exhibit B.

The court **DIRECTS** the Clerk to file a copy of this Order Adopting Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 6 cases identified in the Exhibit attached hereto.

ENTER: July 27, 2018



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

¹ On Exhibit A, I have marked through cases that are closed on the inactive docket or assigned to another District Judge and any cases that could not be identified because of an error in the style or case number.

EXHIBIT A

Clark, Marabeth	2:12-cv-09251
Ingram, Lisa Schneeberger	2:12-cv-09300
Lane, Deborah	2:13-cv-01334
Elliott, Diane	2:13-cv-01740
Paretti, Bonnie Jean	2:13-cv-0821

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Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Elizabeth Mueller, M.D.)

Pending before the court is the Plaintiffs' Motion to Preclude or, in the Alternative, to Limit the Opinions and Testimony of Elizabeth Mueller, M.D. ECF No. 3610] filed by the plaintiffs on April 13, 2017. The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 16,000 cases currently pending, approximately 10,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon Inc. (collectively "Ethicon"), among others.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara

J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 243, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 243, at 4.¹

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties’ misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony

¹ The plaintiffs identified the Wave 4 cases affected by this Motion in their attached Exhibit A [ECF No. 3610], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my

interest in accuracy counsels reserving ruling until the reliability of the expert testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of “junk science” looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court’s prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal

Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

a. Warnings

Plaintiffs seek to prevent Dr. Mueller from testifying regarding the adequacy of Ethicon's TVT and TVT-O warnings. Defendants respond that, "Dr. Muller will not be offering opinions about what should or should not be included in an IFU." Defs' Resp. at 6 [ECF No. 3757]. Instead, defendants assert that Dr. Mueller will give opinions about risks that are within the common knowledge of surgeons who perform pelvic-floor surgery. The risks of pelvic-floor procedures learned through clinical training and professional development are irrelevant to whether Ethicon's TVT and TVT-O warnings at issue here were sufficient. And whether a doctor relies on an IFU in his or her practice is not helpful to a jury. The pertinent issue is that the IFU enumerate the potential adverse events associated with the device, regardless of what independent knowledge a physician might have regarding the risks of pelvic-floor procedures. Accordingly, Dr. Mueller's expert testimony on these matters is **EXCLUDED** and plaintiffs' Motion is **GRANTED** on this limited point.

b. Design

The plaintiffs claim Dr. Mueller is not qualified to offer opinions about the design of the mesh. Ethicon states that Dr. Mueller will not offer opinions about product development and the design process. Accordingly, the plaintiffs' Motion is **DENIED as moot** as to these matters.

c. Properties of the Mesh

The plaintiffs seek exclusion of Dr. Mueller's opinions regarding degradation, fraying, weight, density, porosity and cut (laser or mechanical) of the polypropylene mesh on several grounds.

First, the plaintiffs argue that Dr. Mueller is unqualified because she lacks experience in material science, has not studied or tested polypropylene, and lacks training in the scientific, chemical, or structural makeup of the device at issue. I disagree. Dr. Mueller is a board-certified obstetrician and gynecologist with extensive experience treating women with pelvic floor disorders. She has performed over 1,000 sling procedures using various TVT mesh devices. This, combined with Dr. Mueller's review of the relevant medical literature, qualifies Dr. Mueller to opine on mesh's reaction to and effect on the human body. The plaintiffs' Motion is **DENIED** on this matter.

Second, the plaintiffs challenge the reliability—or lack thereof—of Dr. Mueller's methodology. Dr. Mueller claims to have based her opinions on her clinical experience, leadership roles on various pelvic medicine related professional organizations, and her review of the medical literature. In the abstract, these are reliable bases on which to form an expert opinion.

However, the court is unable to judge the reliability of Dr. Mueller's observations without more information about her methodology. *See* Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts."). Perhaps Dr. Mueller did not observe a significant difference between the TVT mechanically cut versus laser cut because she was not looking. Or perhaps her method of identifying degradation is not

scientifically sound. Additionally, the expert report indicates that Dr. Mueller reviewed a list of literature in forming opinions generally, but the court is directed to minimal specific support for the statements at issue or detail about Dr. Mueller's methodology.

I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony based on a doctor's experience *not* observing something, either in her clinical practice or in the scientific literature. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible

prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 (“[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value.”). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors “to erroneously conclude that regulatory compliance proved safety.” *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon’s compliance with or violation of the FDA’s labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon’s compliance with design control and risk management standards. Some of this testimony involves the FDA’s quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and

document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of

these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (“[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (“Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.”). Additionally, an expert may not offer expert testimony using “legal terms of art,” such as “defective,” “unreasonably dangerous,” or “proximate cause.” *See Perez v. Townsend Eng’g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer

testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

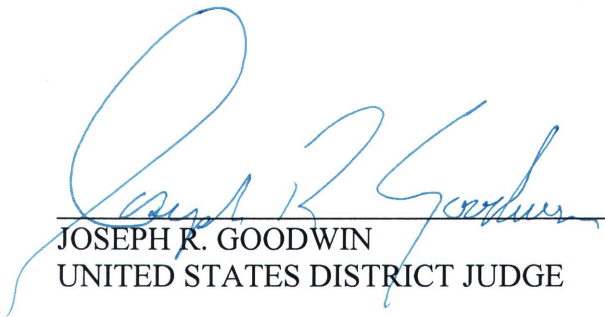
Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be exclude, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part, GRANTS in part**, and **RESERVES in part** the Plaintiffs' Motion to Preclude or, in the Alternative, to Limit the Opinions and Testimony of Elizabeth Mueller, M.D. [ECF No. 3610].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 4 cases identified in the Exhibit attached hereto.

ENTER: July 23, 2018



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE